



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0348 5 APR 11 P2:07

APR 8 2005

Re: Geodon
Docket No.: 03E-0259

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,831,031, filed by Pfizer, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Geodon, the human drug product claimed by the patent.

The total length of the regulatory review period for Geodon is 3,933 days. Of this time, 2,511 days occurred during the testing phase and 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 3, 1990.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 3, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: March 17, 1997.

FDA has verified the applicant's claim that the new drug application (NDA) for Geodon (NDA 20-825) was initially submitted on March 17, 1997.

3. The date the application was approved: February 5, 2001.

FDA has verified the applicant's claim that NDA 20-825 was approved on February 5, 2001.

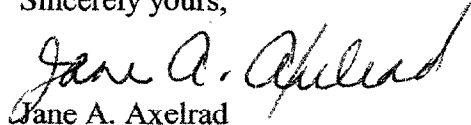
03E-0259

LET 2

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(0349 5 APR 11 P2:07

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Grover P. Fuller, Jr.
Pfizer, Inc.
Legal Division
235 East 42nd Street
New York, NY 10017